

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0701243	(X3) Date Survey Completed 09/13/2021
Name of Provider or Supplier Valley Gastroenterology Assoc	Street Address, City, State 100 Knowlson Avenue, Beaver Falls, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of Laboratory's procedures and interview with the testing personnel (TP)#2, the laboratory failed to establish a procedure that includes the six components required for competency assessment for 1 of 1 Histotechnologist who performed grossing and inking examinations from 09/13/2019 to the date of survey. Findings include: 1. On the day of survey, 09/13/2021 at 02:00 p.m., the TP#2 could not provide a policy that reviews how to assess the competency for 1 of 1 Histotechnologist who performed grossing and inking examinations for 2019, 2020, and 2021. 2. The TP confirmed the finding above on 09/13/2021 around 02:45 p.m.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) documents and interview with the testing personnel (TP)#2, the laboratory failed to establish a quality assurance policy from 09/13/2019 to the date of survey. Findings Include: 1. On the day of survey, 09/13/2021,</p>

the laboratory could not provide a policy for monitoring its pre-analytical, analytical, and post analytic programs from 09/13/2019 to the date of survey. 2. On 09/13/2021 around 02:15 p.m., the TP#2 provided QA activities performed on a monthly basis for 2020 and 2021, but could not produce a policy describing how quality systems are assessed. 3. The TP#2 confirmed the findings above on 09/13/2021 around 2:45 p.m.